REMARKS

Claims 14-34 are presently pending in the Application and claim 34 is withdrawn from consideration in accordance with the election of Group I, claims 14-33, in response to the requirement for restriction.

The Examiner rejects claims 14-33, under 35 U.S.C. § 112, as containing language not supported by the original disclosure and, in particular, the term "faceplate mandrel". In response, the term "faceplate mandrel" is amended to be "main body mandrel" which, as pointed out by the Examiner, is the correct term which is supported by the original disclosure. This amendment is fully supported by the disclosure as originally filed and does not add any new matter to the disclosure or claims. The Applicant, therefore, respectfully requests that the Examiner reconsider and withdraw all rejections of the claims under 35 U.S.C. § 112.

Claims 14-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-9 of U.S. Patent No. 6,533,983 B2 (Curti `984). The Applicant acknowledges and respectfully traverses the raised double patenting rejection in view of the following remarks.

The Applicant thanks the Examiner for indicating that a timely filed Terminal Disclaimer, in compliance with 37 CFR 1.321(c), would overcome the raised double patenting rejection provided that the conflicting application or patent is shown to be commonly owned with this application. In view of this indication, a Terminal Disclaimer, in compliance with 37 CFR 1.321(c), is submitted along with the associated official fee. The United States Patent Office's records shown the common ownership of the above identified application and the conflicting application or patent. In view of the foregoing, it is respectfully submitted that the raised double patenting rejection should be withdrawn at this time.

Next, claims 14-33 are rejected over the prior art cited by the Examiner. In particular, the Examiner rejects:

claim 14 under 35 U.S.C. § 103 over Havstad `900 in view of Collette et al. `818 and in further view of EP 0 933 094 A2,

claims 14-19, 22-23, 26-27 and 29-33 under 35 U.S.C. § 103 over Salter `505 in view of Ventimiglia et al. `116 and in further view of Havstad `900 and EP 0 933 094 A2,

claims 20-21 and 24 under 35 U.S.C. § 103 over Salter `505 in view of Ventimiglia et al. `116 and in further view of Havstad `900, EP 0 933 094 A2 and Lindberg ` 381, and

claim 25 under 35 U.S.C. § 103 over Salter `505 in view of Ventimiglia et al. `116 and in further view of Havstad `900, EP 0 933 094 A2 and Winder `357.

The Applicant acknowledges and respectfully traverses all of the raised obviousness rejections in view of the following remarks.

First considering the present invention as recited in independent claim 14, the recitations of which are generally representative of the recitations in independent claims 27 and 33, the present invention is directed to a method of forming a cannula. According to the present invention, the method of the present invention includes the steps of assembling a cannula mandrel assembly comprising separable engageable parts including a main body mandrel, at least one nasal prong mandrel, and a mouthpiece mandrel including a fluid passage prong having a first end to connect with the main body mandrel and a retainer prong spaced apart from and extending along the fluid passage prong and having a first end terminating adjacent the main body mandrel. The cannula mandrel assembly is then heated to a desired temperature and at least one coating of an uncured cannula forming polymeric material in a flowing state is applied to the cannula mandrel assembly and is at least partially cured on the cannula mandrel assembly.

According to the present invention as recited in the claims, the cannular mandrel assembly is then removed from the cannula by disassembling the cannula mandrel assembly components by withdrawing the at least one prong mandrel, the mouthpiece mandrel including the fluid passage prong and the retainer prong and the main body mandrel from the formed cannula. A shape retaining material is then introduced into a retainer passage formed by the

retainer prong, and the shape retaining material allows the mouthpiece to be adjusted into a desired shape and position and to retain the mouthpiece in that desired shape and position.

Turning now to the prior art cited by the Examer, it is noted that the Havstad `900 reference relates a method for forming a cannula wherein a single piece core is inserted into a mold cavity, the cannular material is injected into the mold, the mold is opened to remove the cannula, the cannula is cut open in order to remove the one piece core, and the cut is welded to restore the integrity of the cannula.

It is, therefore, apparent that Havstad `900 has no teachings, suggestions and/or motivations that are relevant or pertinent to the present invention. For example, the present invention does not employ a cavity mold or injection molding but uses only a cannula mandrel assembly that is dipped in or otherwise coated by the cannula material, the cannula mandrel assembly of the present invention is a multi-component assembly instead of the single piece assembly as specifically taught by Havstad `900, and the cannula mandrel assembly of the present invention is removed from the cannula by disassembly and removal of the individual components while leaving the cannula as a single integral piece instead of by cutting the cannula open and later repairing the slit by which the single piece core was removed.

The Applicant, therefore, respectfully submits that Havstad `900 has no teachings, suggestions or motivations relevant to the present invention under the requirement and provisions of either 35 U.S.C. § 102 or 35 U.S.C. § 103 and the present invention, as recited in independent claims 14, 27 and 33, is thus fully and patentably distinguished over and from Havstad `900 for the reasons discussed above.

It must be further noted that the recitations of independent claims 14, 27 and 33 are incorporated by dependency into all dependent claims, so that all dependent claims are likewise fully and patentably distinguished over and from Havstad `900 for the reasons discussed above.

Turning now to Collette et al. `818, this reference relates to a method for molding a bottle having a neck region molded from material having different properties, that is, more crystalline, than the body of the bottle by using a single mold core and two mold cavity sets at

two temperatures in order to obtain the differing properties for the neck and the body materials. According to Collette et al. `818, the neck material is placed on the neck region of the mold core in a neck cavity set at a first temperature and molded into the desired neck shape with the mold core then being transferred to a body cavity set wherein the body material is molded onto the neck region and formed to the desired body shape at a different temperature.

It is, therefore, apparent that Collette et al. `818 has no teachings, suggestions or motivations that are relevant or pertinent to the present invention. For example, the present invention does not employ even a single cavity mold, much less two separate cavity sets, employs a multi-piece core instead of a single piece core, forms the cannula from a single material having a single set of properties instead of two materials having different properties, requires that the molding be done at only one temperature instead of at two different temperatures in order to obtain differing properties in the molded materials, and is directed to a method for forming a nasal cannula, not a bottle which has no relationship in form, function or manufacturing requirements to a nasal cannula.

It is thus respectfully submitted that Collette et al. `818 has no teachings, suggestions or motivations relevant to the present invention, under the requirement and provisions of either 35 U.S.C. § 102 or 35 U.S.C. § 103, and that the present invention, as recited in independent claims 14, 27 and 33, is fully and patentably distinguished over and from Collette et al. `818 for the reasons discussed above. It must be further noted that the recitations of independent claims 14, 27 and 33 are incorporated by dependency into all dependent claims, so that all dependent claims likewise are fully and patentably distinguished over and from Collette et al. `818 for the reasons discussed above.

EP 0 933 094 A2 and Salter `505 each describe a nasal cannula having nasal prongs wherein the EP 0 933 094 A2 includes an oral prong and a gas collection tube. Except that Salter `505 briefly notes that the cannula is formed by a dip molding process, neither reference has any description, discussion or disclosure concerning the method by which a cannula is formed, but instead only describes the final form of the cannula. As noted by the Examiner in

the restriction requirement, the method by which a product is formed is separate inventive subject matter from the form of the product.

As such, it is respectfully submitted that neither EP 0 933 094 A2 nor Salter `505 has any teachings, suggestions or motivations relevant to the method for forming a cannula and, in particular, neither EP 0 933 094 A2 nor Salter `505 describes or suggests a method that includes the steps of assembling a cannula mandrel assembly comprising separable engageable parts including a main body mandrel, at least one nasal prong mandrel, and a mouthpiece mandrel including a fluid passage prong having a first end to connect with the main body mandrel and a retainer prong spaced apart from and extending along the fluid passage prong and having a first end terminating adjacent the main body mandrel, coating the cannula mandrel assembly with a polymeric material, and removing the cannular mandrel assembly from the cannula by disassembling the cannula mandrel assembly by withdrawing the at least one prong mandrel, the mouthpiece mandrel including the fluid passage prong and the retainer prong and the main body mandrel from the formed cannula.

It is therefore the Applicant's position that neither EP 0 933 094 A2 nor Salter `505 has any teachings or suggestions relevant to the present invention, under the requirement and provisions of either 35 U.S.C. § 102 or 35 U.S.C. § 103, and the present invention, as recited in independent claims 14, 27 and 33, is fully and patentably distinguished over and from EP 0 933 094 A2 and Salter `505 for the reasons discussed above. It must be further noted that the recitations of independent claims 14, 27 and 33 are incorporated by dependency into all dependent claims, so that all dependent claims are likewise fully and patentably distinguished over and from EP 0 933 094 A2 and Salter `505 for the reasons discussed above.

With respect to Ventimiglia et al. `116, this reference relates to a method for forming an article by dip molding of a heated one piece mold into successive different materials so that the article is formed of layer of differing properties, such as a foamed layer and one or more skin layers. It is therefore apparent that the only possible relevance of Ventimiglia et al. `116 to the present invention is the dip molding of a heated form which, while recited in certain of the

dependent claims, is not an essential part of the present invention, as recited in independent claims 14, 27 and 33.

The fundamental distinctions between the present invention, as recited in independent claims 14, 27 and 33, and the teachings and suggestions of Ventimiglia et al. `116 are apparent from the above discussions and are the same as those discussed above with respect to Havstad `900, Collette et al. `818, EP 0 933 094 A2 and Salter `505. Again, as discussed previously, Ventimiglia et al. `116 does not teach or suggest a method for forming a cannula that includes the steps of assembling a cannula mandrel assembly comprising separable engageable parts including a main body mandrel, at least one nasal prong mandrel, and a mouthpiece mandrel including a fluid passage prong having a first end to connect with the main body mandrel and a retainer prong spaced apart from and extending along the fluid passage prong and having a first end terminating adjacent the main body mandrel, coating the cannula mandrel assembly with a polymeric material, and removing the cannular mandrel assembly from the cannula by disassembling the cannula mandrel assembly by withdrawing the at least one prong mandrel, the mouthpiece mandrel including the fluid passage prong and the retainer prong and the main body mandrel from the formed cannula.

It is therefore the Applicant's position that Ventimiglia et al. `116 has no teachings or suggestions relevant to the present invention, under the requirement and provisions of either 35 U.S.C. § 102 or 35 U.S.C. § 103, and the present invention, as recited in independent claims 14, 27 and 33, is fully and patentably distinguished over and from Ventimiglia et al. `116 for the reasons discussed above. It must be further noted that the recitations of independent claims 14, 27 and 33 are incorporated by dependency into all dependent claims, so that all dependent claims are likewise fully and patentably distinguished over and from Ventimiglia et al. `116 for the reasons discussed above.

Turning now to Lindberg ` 381, this reference relates to the use of a mold release agent with a beryllium-copper mold or mandrel thus has some relevance to certain of the dependent claims, such as claims 20 and 24, but has no teachings or suggestions relevant to the

recitations of independent claims 14, 27 and 33. The fundamental distinctions between the present invention, as recited in independent claims 14, 27 and 33, and the teachings and suggestions of Lindberg ` 381 are apparent from the above discussions and are the same as those discussed above with regard to Havstad `900, Collette et al. `818, EP 0 933 094 A2 and Salter `505. It is, therefore, the Applicant's position that Lindberg ` 381 has no teachings or suggestions relevant to the present invention under the requirement and provisions of either 35 U.S.C. § 102 or 35 U.S.C. § 103 and that the present invention, as recited in independent claims 14, 27 and 33, is fully and patentably distinguished over and from Lindberg ` 381 for the reasons discussed above. It must be further noted that the recitations of independent claims 14, 27 and 33 are incorporated by dependency into all dependent claims, so that all dependent claims are likewise fully and patentably distinguished over and from Lindberg ` 381 for the reasons discussed above.

With respect to Winder `357, this reference relates to a molding process that uses a plurality of dipping steps and thus may have some relevance to, for example, dependent claim 25, but has no teachings or suggestions relevant to the recitations of independent claims 14, 27 and 33. The fundamental distinctions between the present invention as recited in independent claims 14, 27 and 33 and the teachings and suggestions of Winder `357 are apparent from the above discussions and are the same as those discussed above with regard to Havstad `900, Collette et al. `818, EP 0 933 094 A2 and Salter `505.

It is, therefore, the Applicant's position that Winder `357 has no teachings or suggestions relevant to the present invention under the requirement and provisions of either 35 U.S.C. § 102 or 35 U.S.C. § 103, and that the present invention, as recited in independent claims 14, 27 and 33, is fully and patentably distinguished over and from Winder `357 for the reasons discussed above. It must be further noted that the recitations of independent claims 14, 27 and 33 are incorporated by dependency into all dependent claims, so that all dependent claims are likewise fully and patentably distinguished over and from Winder `357 for the reasons discussed above.

Lastly, considering the consequences of various combinations of Havstad `900, Collette et al. `818, EP 0 933 094 A2, Salter `505, Ventimiglia et al. `116, Lindberg ` 381 and/or Winder `357 with one another, and rather than considering each of the cited combinations individually, the Applicant wishes to point out that none of the cited references in any way teaches, suggests or discloses a method for forming a cannula that includes the steps recited in independent claims 14, 27 and 33 of assembling a cannula mandrel assembly comprising separable engageable parts including a main body mandrel, at least one nasal prong mandrel, and a mouthpiece mandrel, coating the cannula mandrel assembly with a polymeric material, and removing the cannular mandrel assembly from the cannula by disassembling the cannula mandrel assembly by withdrawing the at least one prong mandrel, the mouthpiece mandrel. For these reasons, there is not and cannot be any combination of Havstad `900, Collette et al. `818, EP 0 933 094 A2, Salter `505, Ventimiglia et al. `116, Lindberg ` 381 and/or Winder `357 that in any way teaches, suggests or discloses the invention, as recited in independent claims 14, 27 and 33, to those of ordinary skill in the arts under the requirements and provisions of 35 U.S.C. § 103. In addition, and because the recitations of independent claims 14, 27 and 33 are incorporated into each of the dependent claims by dependency, each of the dependent claims is thereby fully and patentably distinguished over and from all combinations of Havstad `900, Collette et al. `818, EP 0 933 094 A2, Salter `505, Ventimiglia et al. `116, Lindberg ` 381 and/or Winder `357 for at least the same reasons that independent claims 14, 27 and 33 are fully and patentably distinguished over and from Havstad `900, Collette et al. `818, EP 0 933 094 A2, Salter `505, Ventimiglia et al. `116, Lindberg ` 381 and Winder `357.

In addition, it must be noted that independent claims 14, 27 and 33 are amended by the addition of the recitation that the mouthpiece mandral further includes a fluid passage prong having a first end to connect with the main body mandrel and a retainer prong spaced apart from and extending along the fluid passage prong and having a first end terminating adjacent the main body mandrel and that a shape retaining material is introduced into a retainer passage formed by the retainer prong, thereby allowing the mouthpiece to be adjusted into a desired

position and shape and to retain that desired position and shape. It must be noted that these aspects of the present invention are fully supported by the disclosure as originally filed, such as in FIGS. 10, 11 and 12 and the corresponding portions of the text of the disclosure, that these amendments have not added any no matter to or altered the scope or subject matter of the disclosure or claims.

In summation, it is respectfully submitted that no valid combination of Havstad `900, Collette et al. `818, EP 0 933 094 A2, Salter `505, Ventimiglia et al. `116, Lindberg ` 381 and/or Winder `357 in any way teaches, suggests or discloses this aspect of the present invention under the requirements and provisions of 35 U.S.C. § 103, and all of the pending claims are fully patentably distinguished over and from any and all combinations of the cited prior art. For the above reasons, therefore, the Applicant respectfully requests that the Examiner reconsider and withdraw all rejections of the claims as presented herein over the cited prior art, and the allowance of the claims as presented herein.

If any further amendment to this application is believed necessary to advance prosecution and place this case in allowable form, the Examiner is courteously solicited to contact the undersigned representative of the Applicant to discuss the same.

In view of the above amendments and remarks, it is respectfully submitted that all of the raised rejection(s) should be withdrawn at this time. If the Examiner disagrees with the Applicant's view concerning the withdrawal of the outstanding rejection(s) or applicability of the Havstad `900, Collette et al. `818, EP 0 933 094 A2, Salter `505, Ventimiglia et al. `116, Lindberg ` 381 and/or Winder `357 references, the Applicant respectfully requests the Examiner to indicate the specific passage or passages, or the drawing or drawings, which contain the necessary teaching, suggestion and/or disclosure required by case law. As such teaching, suggestion and/or disclosure is not present in the applied references, the raised rejection should be withdrawn at this time. Alternatively, if the Examiner is relying on his/her expertise in this field, the Applicant respectfully requests the Examiner to enter an affidavit substantiating

the Examiner's position so that suitable contradictory evidence can be entered in this case by the Applicant.

In view of the foregoing, it is respectfully submitted that the raised rejection(s) should be withdrawn and this application is now placed in a condition for allowance. Action to that end, in the form of an early Notice of Allowance, is courteously solicited by the Applicant at this time.

The Applicant respectfully requests that any outstanding objection(s) or requirement(s), as to the form of this application, be held in abeyance until allowable subject matter is indicated for this case.

In the event that there are any fee deficiencies or additional fees are payable, please charge the same or credit any overpayment to our Deposit Account (Account No. 04-0213).

Respectfully submitted,

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